

**Notice of Allowability**

Application No.

09/612,809

Examiner

Gerald G Leffers Jr., PhD

Applicant(s)

SCHEFFIELD, ET AL

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the reply filed 4-19-2004.
2. ☒ The allowed claim(s) is/are 11-13 and 15-23.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☒ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 8/28/2003
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

### **EXAMINER'S AMENDMENT**

Receipt is acknowledged of an amendment, filed 4/19/2004, in which several claims were amended (claims 11, 18-19, 22-23). Prior to entry of this examiner's amendment, claims 11-24 were pending.

The following examiner's amendment is made to update the status of a parent application, 09/083,351, to which the instant application claims priority. In addition, the Brief Description of the Drawings is amended for Figure 2 to ensure that the appropriate SEQ ID NOS for the sequences shown in Figure 2 are present. Finally, two product-by-process claims are cancelled (claims 14 and 24).

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Steven L. Highlander on ~19 July 2004.

The application has been amended as follows:

In the specification:

At page 1, first sentence of the specification, the following claim for priority to the parent applications has been inserted:

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--This application is a divisional application based on U.S. Serial No. 09/083,351, filed on 5/22/1998 and now U.S. Patent No. 6,087,107, which itself claims priority to provisional patent application 60/081,870, filed April 15, 1998 and now abandoned.--

At pages 7-8, bridging paragraph, the Brief description of the Drawings for Figure 2 has been amended by inserting --(SEQ ID NOS: 4-20)-- immediately after the word "genes" at the end of the first sentence, but prior to the period at the end of the first sentence. The amended sentence should read "FIG. 2 shows an amino acid comparison of the forkhead domains of different members of the FKHL-family of genes (SEQ ID NOS: 4-20)."

In the claims:

Claims 14 and 24 have been cancelled.

In the Title:

The title has been deleted and replaced with the following new title:

--Methods to Identify Modulators of FKHL7 DNA-Binding Activity--

***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance: applicants' arguments and amendment of the claims in the response filed 4/19/2004 have obviated the outstanding

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grounds of rejection for the allowed claims. In particular, applicants correctly point out that the DNA binding site for FKHL7 (or FREAC3) was known in the art at the time of the invention (see Pierrou et al, EMBO Journal, 1994, Vol. 13, pages 5002-5012, e.g. Figure 3; see also Larsson et al, Genomics, 1995, Vol. 30, pages 464-469, e.g. the abstract, for evidence that FREAC3 is another name for FKHL7). Further, the specification points to the core DNA sequence bound by this class of "Forkhead" proteins (e.g. page 1, lines 31-32). Therefore, the skilled artisan could reasonably have envisioned DNA sequences that specifically bind FKHL7 and would have been able to practice the claimed invention without undue experimentation.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### ***Information Disclosure Statement (IDS)***

Receipt is acknowledged of an IDS filed 8/28/2003. The signed and initialed PTO Form 1449 has been mailed along with this action. Each of the documents cited thereon have been considered in full.

#### ***Drawings***

The drawings filed on 11/17/2000 are acceptable subject to correction of the following informalities. The drawings are objected to because the margins are too small (i.e. the top margin for the Figure 1 sheets and the left margin for Figures 2 & 3). In order to avoid

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abandonment of this application, correction is required in reply to the Office action. The correction will not be held in abeyance.

***Conclusion***

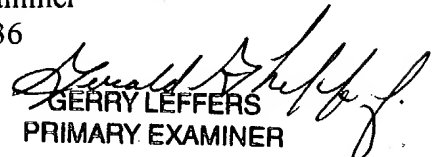
Claims 11-13, 15-23 are allowed (now claims 1-12).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636

  
GERY LEFFERS  
PRIMARY EXAMINER

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